

Short report

Deproteinised latex condoms are well tolerated by latex allergic patients

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Immediate hypersensitivity reactions to natural rubber latex were first recognised in 1979.¹ Since the late 1980s, latex allergy has been recognised as a major problem, especially in individuals such as healthcare workers who use latex gloves at work every day^{2,3} and in patients heavily exposed to latex gloves—for example, children who undergo multiple surgical interventions for congenital neurological or urological abnormalities.⁴ Condoms, widely used as a means of contraception and/or to prevent sexually transmitted diseases, were among the first latex products reported to cause an allergic reaction—going from genital urticaria to anaphylaxis—in individuals who had become sensitised to latex.^{5–8} This is not surprising given that classic latex condoms may contain as much latex allergen as latex gloves.^{9,10}

Among latex allergic people who use condoms, these reactions are not rare.^{6,8} We recently questioned 238 of our latex allergic patients—mostly women, and half of them healthcare professionals—about their use of condoms¹¹; 39% reported having used condoms at least once since becoming allergic to latex. The large majority (84%) of those who had used condoms reported having had a local and/or a generalised immediate hypersensitivity reaction on contact with a condom during sexual intercourse. Local itching and swelling were the most frequently reported complaints, but at least one fourth of them had also had cutaneous urticaria, angioedema, and/or respiratory symptoms, leading them to no longer use condoms. Many of these patients said that they would be happy to use condoms that did not cause them to have an allergic reaction.

Since 1996, Ansell France (Cergy-Pontoise, France) has marketed a *deproteinised* latex condom (Manix Crystal) in France and other European countries. Because it was not known if latex allergic people tolerated these condoms, we investigated this in an open study.

Nineteen adults (14 women, including 13 healthcare professionals, and five men, including two healthcare workers) with documented latex allergy who were unable to use classic latex condoms because they had previously had one or more allergic reactions when using them were included in this ethics committee approved study after signing a consent form. All had experienced genital pruritus shortly after contact with a classic latex condom during sexual intercourse. A third of them also reported genital oedema at the same time as the pruritus. A few reported having had urticaria elsewhere. These symptoms affected men and women equally. One woman reported

that she had experienced asthma-like dyspnoea and wheezing when she had contact with a classic latex condom. The symptom(s) began within less than 30 minutes and nearly always within the first hour after contact with the condom. Most subjects were prudent: after once or twice having had a reaction, they no longer used a latex condom during sexual intercourse. Still, most of them said that they would prefer to use condoms for contraception. In a few cases, the reaction was mild and they continued to use classic latex condoms for several more years.

At entry, each subject had a skin prick test (SPT) through a Manix Crystal condom and a classic Manix latex condom (a positive condom control). The total protein content of this classic latex condom was 38 µg/g condom, whereas the total protein content and the latex antigen content of the Manix Crystal condom were below the level of detection in our laboratory.¹² A positive SPT is indicated by a weal of ≥ 3 mm with surrounding erythema. Seventeen of 19 patients had a positive SPT to the classic condom whereas none reacted to the Crystal condom. As an additional control, an intact Manix Crystal condom was placed on each subject's left thumb for a maximum of 15 minutes; none of the patients reacted to this challenge.

Each patient was given 12 Manix Crystal condoms, to be used over a period of 6 weeks, and a diary form to be filled out each time a condom was used. The principal outcome criterion was the proportion of latex allergic patients who are able to use the Manix Crystal condoms without local and/or systemic symptoms or signs of an immediate hypersensitivity reaction.

All 19 patients used all 12 of the Manix Crystal condoms during the 6 week study period and none had an allergic reaction or any other adverse event on or after contact with these condoms. During the same period, one subject had eczema on her hands and a conjunctival reaction induced by latex medical gloves and another had a systemic allergic reaction induced by contact with a small latex bearing adhesive sticker.

The present results demonstrate that the Manix Crystal deproteinised latex condom induces significantly fewer reactions than reported by latex allergic patients when they had previously used classic latex condoms ($\chi^2=45$; $p<0.0001$). We recognise that the number of patients who participated in the present study is limited. At the end of the 6 week study period, the patients were given an additional supply of these deproteinised condoms and they used

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them without incident for at least an additional 6 months providing further evidence that they are safe for use in latex allergic patients.

Although most IgE mediated reactions induced on contact with latex condoms are localised to the vulva or penis, condoms can cause serious systemic allergic reactions, such as asthma or anaphylaxis.^{5,6,8} Among the 94 cases we described previously, one quarter of the 94 patients reported systemic symptoms.¹¹ In the present investigation, three of the patients reported that they had previously experienced rhinoconjunctival symptoms and two had experienced dyspnoea and wheezing after intercourse. To our knowledge, there have been no fatal allergic reactions caused by latex condoms.

Latex condoms could theoretically be a source of sensitisation to latex for both women and men. Physical contact of latex gloves with mucous membranes is considered to be an important route of sensitisation to latex.⁴ Thus, the vaginal mucosa could be such a route. Moreover, the skin of the penis is very thin and mobile and this might allow latex proteins to be absorbed, leading to sensitisation in susceptible men. To our knowledge, there are no reports of this occurring, although we have seen one latex allergic male patient who used latex condoms regularly and who claimed not to have had occupational exposure to latex gloves (F Leynadier, personal observation).

In conclusion, Manix Crystal deproteinised latex condoms appear to be a safe alternative to abstinence for the prevention of sexually transmitted diseases and pregnancy for latex allergic patients.

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Contributors: All three authors collaborated in planning the study and in the preparation of the protocol; PM recruited the patients in the Centre d'Allergologie Consultation Service at the Hôpital Tenon; FL is the director of that centre; PM saw the patients at the beginning and at end of the study. Data were reviewed and analysed simultaneously by all three investigators at the end of the study. DAL was responsible for preparation of the draft of the manuscript; the final document was reviewed and corrected by all three authors.

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